## REMARKS

The Office Action mailed June 15, 2007 has been carefully considered. Claims 1, 2, 5-11, 13-22 and 24-37 were pending in the application and were rejected.

The amendments to the Specification do not add new matter. Applicant merely moved the statement from one section of the document to another, after realizing it was mislocated.

**35 USC § 103**

Claims 1-2, 5-11, 13-22, 24-27, 30-34 and 36-37 were rejected under 35 USC § 103(a) as being unpatentable over Ghosal (US 6,362,167) in view of Ghosal (US 6,440,436) as evidenced by Pushppangadan et al. (US 2003/0185913) and in further view of Boynton et al. (5,087,623). Applicant traverses the rejection.

The Examiner relied on Pushpandagadan (at page 2, para. 0014) for the evidence that herbal health compositions can be used to control blood sugar levels in patients with diabetes. The statement in Pushpandagadan does not refer to any and all herbal health compositions; it was a statement made with respect to the Pushpandagadan inventive composition, which does not contain either Shilajit or *Phyllanthus emblica*. (See Pushpandagadan at page 3, paragraphs [0017] and [0018] and claims 1, 3, 10 or 21).

The Examiner relied on Pushpandagadan (at page 9-10, Table 1) for the evidence that commercial herbal anti-diabetic products contain Shilajit and *Phyllanthus emblica*. Applicant concedes that Table 1 contains a column under the heading "Commercial herbal antidiabetic products" which contains a product called "Madhumeh Amrit" containing a wide variety of herbs including Shilajit and *Phyllanthus emblica*. However, what Pushpandagadan says about these commercial herbal antidiabetic products teaches away from finding them to be useful. Pushpandagadan teaches that "Most of the products (a list given in Table 1) are a mixture of herbs/medicinal plants, minerals, and bhasams (ashes) *without a suitable balanced nutritional composition to ameliorate the general health of diabetics and none of them is a nutraceutical.*" Pushpandagadan finishes by teaching: "To the best of the Applicant's knowledge no nutraceutical comprising a combination of legumes, cereals, pseudocereals fortified with herbs/medicinal plants used in the present invention or a process for the preparation of the same exist for diabetic patients."(See page 2, para. [0007]).

Thus the Examiner's conclusion that Pushpandagadan teaches that the extract from the fruit of *Emblica officinalis* plant and purified shilajit can be used to treat hyperglycemia in patients with diabetes (Office Action, page 5, top) is not based on evidence in, or on a proper analysis of, the Pushpandagadan patent application. The Examiner failed to consider statements that teach away from using the commercial products in the manner relied upon by the Examiner and the Examiner mis-attributed Pushpandagadan's statement about the benefits of its own invention, thinking it was a statement about the prior art commercial products.

In light of that error, the Examiner's conclusion was error that it would have been obvious to employ the Emblica and Shilajit extracts described in the two Ghosal patents (US'167 and US '436), respectively, to contain chromium, relying on the erroneous analysis of the Pushpandagadan application. The Examiner also used the erroneous analysis of Pushpangadan as a basis for a motivation to combine all the ingredients. Thus, no motivation for the combination has been given based on rational grounds or on proferred evidence.

Notwithstanding, that the entire grounds for combining the references were based on an improper conclusion, without real evidence, Applicant presents further secondary evidence to rebut the obviousness rejections.

Secondary evidence of non-obviousness under *Graham v. John Deere*, includes a showing of long felt but unsolved need. In the present case, although prior art showed that chromium (III) can be used to control high blood serum glucose levels, the problem that was not solved by the prior art was that chromium (III) as a dietary supplement, is converted to toxic chromium (VI) by spontaneous systematic oxidation and hence induces delayed toxicity. (See Specification, Description of Prior Art at page 5, first paragraph). Thus, studies of chromium (III) picolinate and niacin-bound chromium (III), two popular dietary supplements, revealed that chromium (III) picolinate produces significant oxidative stress and DNA damage. (See Specification, page 5, second paragraph). In response to this need, an object of the claimed invention was to provide a composition for treating diabetes or glucose intolerance by employing a safe and effective phenolic antioxidant-chromium complex, without pro-oxidation activity. To this effect, the inventor discovered a particular antioxidant–ligand for chromium that prevents the chromium from being systemically converted from Chromium (III) to Chromium (VI). Thus

the claimed invention is for a composition that comprises a phenolic antioxidant, that has no pro-oxidation activity, complexed with chromium. The inventor found that the phenolic antioxidant that is obtained from shilajit or from *Phyllanthus emblica* or certain other plants provides the safe phenolic antioxidant complex that avoids the conversion of chromium (III) to chromium (VI). This is because the phenolic antioxidants are capable of occupying all the available coordination sites in chromium, thereby eliminating the possibility of forming an undesirable oxo-chromium complex. (See specification at page 10, under the heading "Phenolic Antioxidant(s)"). Thus, there was a long felt but unsolved need that is solved with this invention.

Furthermore, it is accepted law that when the invention is more than the predictable use of prior art elements according to their established function, the invention is not obvious. More particularly, the Supreme Court has reiterated that the fact that the individually known elements work together in an unexpected and fruitful manner support the conclusion of non-obviousness. (*KSR International Co. v Teleflex Inc.*, No. 04-1350 (550 U.S.__), (April 30, 2007)). The erroneous conclusion of obviousness, here, was because the Examiner reviewed the claimed invention as merely a predictable combination of elements to control high blood serum glucose levels, overlooking the unexpected aspects of the claimed invention, namely that the antioxidant ligand for chromium chosen in this invention is capable of occupying all the available coodination sites in chromium, thereby eliminating the possibility of forming undesirable oxo-chromium complex.

With regard to the Examiner's grounds for rejecting specific dependent claims, Applicant asserts the following. Regarding the particular ranges of chromium in the composition, in claims 7 and 26, Boynton et al. teach a percentage outside of the range for these claims. Boynton's 12.5% is clearly higher than the ranges of .02 to 10% and 1 to 8%, respectively for those claims. The Examiner found the prior art to be close enough, and relied on *In re Aller* for the premise that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. However, the facts in this case do not fit those of *In re Aller*. Namely, as stated above, the prior art did not disclose the general conditions of the claims. The Examiner's conclusion of obviousness was based on a

misread of prior art. As to claims 9, 19 and 27 the Examiner mistakenly based this rejection on an argument as to amount of chromium content in the complex, but these claims are not directed to amount of chromium in the complex. Furthermore, to the extent the Examiner relied on *In re Aller*, as above, the rebuttal argument above applies to these claims as well.

For all the reasons discussed above, Applicant asserts that the claims are patentable over the cited prior art and respectfully requests that the rejections be reconsidered and withdrawn.

Obviousness-Type Double Patenting

Claims 1, 5, 9-11, 13-16, 18, 20, 31, 33 and 36-37 were rejected on the ground of nonstatutory obviousness-type double patenting as unpatentable over claim 8 of Ghosal (US 6,440,436). Applicant traverses the rejection.

Contrary to the Examiner's explanation, claim 8 of US 6,440,436 is not directed to the purified shilajit composition. Claim 8 is directed to a process for producing purified shilajit. As such the Examiner's reasoning is inapplicable to this rejection. The instant rejected claims are all composition claims, thus they are patentably distinct from claim 8.

Furthermore, this rejection is especially inappropriate with respect to claims 10, 11, 13, and 16 which require that the phenolic antioxidant is of the type from particular plant species. US 6,440,436 doeesn't even disclose, let alone claim the plant species. The Examiner gave no explanation or evidence why he concluded that extract of shilajit is the same as extract of the fruit of *Emblica officinalis*.

Claims 1, 5, 9-11, 13-16, 18, 20, 31, 33 and 36-37 were rejected on the ground of nonstatutory obviousness-type double patenting as unpatentable over claim 8 of Ghosal US 6,440,436 and claim 1 of Ghosal US 6,869,612. Applicant traverses the rejection for all the same reasons as stated above.

Claims 1, 5, 9-11, 13-16, 18, 20, 31, 33 and 36-37 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as unpatentable over claims 18, 46, 51 and 55 of Ghosal application identified by publication number US 2006/0062863. Applicant traverses the rejection. Due to a restriction requirement and subsequent election, those claims are no longer in prosecution in the co-pending application.

In view of the foregoing, Applicants submit that all pending claims are in condition for allowance and request that all claims be allowed. The Examiner is invited to contact the undersigned should he believe that this would expedite prosecution of this application. It is believed that no fee is required. The Commissioner is authorized to charge any deficiency or credit any overpayment to Deposit Account No. 13-2165.

Respectfully submitted,

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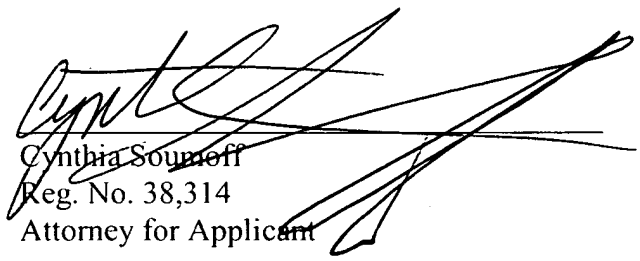

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